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EXAMINER	
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ART UNIT	PAPER NUMBER
2644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,989	MILLER ET AL.	
	Examiner	Art Unit	
	Tony M. Jacobson	2644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9,16-27 and 31-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,16-27 and 31-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claim 9** is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for utilizing a test device to generate at least one predetermined test signal that is provided by the test device to the hearing aid by providing the at least one predetermined test signal to a speaker located external to the patient and utilizing an implanted microphone to receive the acoustic test signal and provide the test signal to an implanted signal processor (e.g., at page 19, lines 11-15 and page 28, lines 1-5), does not reasonably provide enablement for utilizing a test device to generate at least one predetermined test signal that is provided by the test device to the hearing aid by transmitting the at least one predetermined test signal to a speaker located external to the patient, wherein [the at] least one predetermined signal is acoustically provided by the speaker, alone (i.e., without utilizing an implanted microphone to receive the acoustic test signal and provide the test signal to an implanted signal processor). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claim is of such a scope as to cover other inventions not enabled by Applicants' disclosure; for example a method in which the signal is transferred inductively to the implanted hearing aid, and also

reproduced by a speaker so that an operator (e.g., an audiologist) can audibly monitor the tone signal being applied.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claim 37** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. **Claim 37** is directed to two classes of statutory subject matter. The claim attempts to embrace both an apparatus or machine and a process. This is precluded by the language of 35 U.S.C. 101, which sets forth the statutory classes of invention in the alternative only. While a single patent may include claims directed to more than one statutory class of invention, no basis exists for permitting a combination of two separate and distinct classes of invention in a single claim. The claiming of two statutory classes of invention in a single claim is ambiguous and renders the claim indefinite. It appears that Applicant may have intended to recite "The system of claim 21 ...", since claim 21 is directed to a system (apparatus). The following prior-art rejection is based on this assumption.

Claim Rejections - 35 USC § 101

6. **Claim 37** is rejected under 35 U.S.C. 101 because the claimed invention is directed to two classes of statutory subject matter. The claim attempts to embrace both an apparatus or machine and a process. This is precluded by the language of 35 U.S.C. 101, which sets forth the statutory classes of invention in the alternative only. While a single patent may include claims directed to more than one statutory class of invention, no basis exists for permitting a combination of two separate and distinct classes of invention in a single claim. (See explanation under 35 USC 112, second paragraph, above.)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claims 1-5, 7-9, 16-27, 31-33, and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer (US 6,788,790) in view of Leysieffer (US 6,554,762) and Durand (US 6,154,023).

9. Regarding **claims 1 and 20**, Leysieffer '790 generally discloses a system and method for determining the quality of coupling between an implanted hearing aid actuator and an ossicle of a patient's middle ear (column 2, lines 22-31). Leysieffer '790 discloses in Figs. 1-4 and describes at column 6, line 17 –column 8, line 19 fully-implanted embodiments of the invention, in which test signal generation means (as a separate element 90 in Fig. 1, or comprised in digital signal processor 140 or 141 of Figs. 2 and 3, respectively) are included within the signal processing portion (30) of the implanted hearing aid system, which communicates with a programming system (120) transcutaneously and bidirectionally. Leysieffer '790 discloses in Fig. 5 and describes at column 8, lines 20-47 a partially-implanted embodiment of the invention. At column 8, lines 33-37 Leysieffer '790 discloses that the electronic unit (30) of the external system part (210) of the partially implanted hearing aid system of Fig. 5 includes all the electronic components necessary for signal processing and audiometry tone generation, as in the fully-implanted hearing aid embodiments of Figs 1-3. The external system part (210) of the partially-implanted hearing aid system of Fig. 5 thus constitutes a test device, separate from and positionable external to a patient having an implanted hearing aid with an actuator, including a signal generator to generate at least one test signal at a predetermined frequency, wherein said hearing aid passes an electrical signal through the implanted hearing aid actuator in response to said test signal.

Leysieffer '790 does not disclose a measurement device to measure a magnetic field generated by the implanted hearing aid actuator in response to the electrical signal to generate at least one test measure of the electrical signal; nor [that] a signal

processing unit [is configured] to process the at least one test measure to assess at least one performance parameter of the implanted hearing aid.

Although Leysieffer '790 generally indicates a desire to obtain an objective and quantitative measure of the coupling quality of an interface between an implanted hearing aid actuator and a middle-ear ossicle of a patient (e.g., column 2, lines 8-31), only subjective results are obtained by the method and apparatus disclosed, based on conscious (deliberate) patient responses to test signals, or qualitative results by the methods of the prior art described (WO 98/36711), based on electric response audiometry, auditory brainstem response, or electrocochleography.

Leysieffer '762 discloses in Fig. 1, an implantable hearing aid system with means and associated method to objectively obtain a more quantitative measure of the coupling quality of an interface between an implanted hearing aid actuator and a middle-ear ossicle of a patient (a system for assessing the performance of a hearing aid that includes an implanted actuator), which comprises:

a test device including:

a signal generator (DSP 13 in combination with microcontroller 17) to generate at least one test signal at a predetermined frequency, wherein said hearing aid passes an electrical signal through an implanted hearing aid actuator (16) in response to said test signal;

a measurement device (25) to generate at least one test measure (the impedance) of the electrical signal; and

a signal processing unit (13) to process the impedance measure to assess at least one performance parameter of the implanted hearing aid.

Leysieffer '762 does not disclose that the test device is (completely) separate from and positionable external to a patient having the implanted hearing aid, nor that the measurement device measures a magnetic field generated by the implanted hearing aid actuator; rather, the system of Leysieffer '762 determines the test measure (actuator impedance) by measuring a voltage drop across a current sampling resistor ("Rm" in Fig. 2) to determine the associated current, and calculates the impedance as the quotient of the applied voltage (to the actuator) and the thus-determined current through the actuator. In Fig. 11, Leysieffer '762 discloses an embodiment of the invention in which the hearing aid system is a partially-implanted type, similar to that of Fig. 5 of Leysieffer '790, including the elements of Fig. 1 (of the '762 patent, sans telemetry system 20), in which a passive electronics module (74) is implanted along with a transducer (16 or 36), and in which the remainder of the electronics are disposed in an external unit (76). Some specific details of this embodiment are described at column 20, line 64 through column 21, line 13, where it is disclosed that the impedance measuring system (25) of Fig. 1 is included in the implanted portion of the hearing aid system. With regard to the embodiment of Fig. 11, Leysieffer '762 does not disclose any specific details of the interconnection to a programming system or how the impedance measurement data is presented or interpreted, other than reciting at column 21, lines 9-13, "The electronic module 77 and the modulator/transmitter unit 75 include the necessary telemetry unit for transmission of the impedance measuring data to the

external module 76 for further evaluation." One of ordinary skill in the art would reasonably assume that the external unit (76) connects to a programming system, equivalent to that of Figs. 1, 6, and 7 (22), except in this case the connection could be a direct wire connection, rather than a wireless transcutaneous electrical interface, as illustrated in Fig. 5 and described at column 8, lines 37-42 of Leysieffer '790.

At the time the present invention was made, it was conventional to construct partially-implanted hearing aid systems such as that of Fig. 5 of Leysieffer '790 with most of the circuitry contained in the external portion, and with a minimum of componentry included in the implanted portion (e.g., receiving coil, demodulator, and transducer, as described and illustrated in US Patent 5,795,287 to Ball et al., cited by Leysieffer '790 at column 8, lines 29-33); such minimally-complex construction of the implanted portion of the hearing aid system was well known to provide advantages such as reduced size and mass, reduced power transfer requirement across the inherently-inefficient inductive transcutaneous power interface (and thus improved energy efficiency), and probably most importantly, improved reliability of the implanted portion, which is difficult and costly to service or replace. In view of this common knowledge in the art and the teachings of Leysieffer '762, one of ordinary skill would have sought alternative methods to obtaining externally a measure of the actuator impedance of a partially-implanted hearing aid system of the type taught by Leysieffer '790 without requiring in the implanted portion of the hearing aid system additional circuitry for actuator current and voltage sensing and a bidirectional communication interface to

communicate the measured current and voltage values to the external portion of the hearing aid system.

Durand discloses in Fig. 1, a system for remotely measuring a current in an implanted medical device using a pair of sensors to measure a magnetic field generated by the current (column 1, lines 7-13 and 22-26). Durand discloses at column 2, lines 11-17 that the remote current sensor of the invention can be used to sense currents in conductors located at or beneath a surface at locations difficult to reach with existing sensors, non-invasively.

At the time the present invention was made, one of ordinary skill in the art would have recognized that the voltage applied to the actuator (20) in the partially-implanted hearing aid system of Fig. 5 of Leysieffer '790 could be estimated in the external unit (210) based on the level at which a signal is transmitted to the implanted passive electronics module (200) by the external unit.

It would have been obvious to one of ordinary skill in the art at the time the present invention was made to employ the remote current sensing system of Durand, located in the external test unit (210) of the partially-implanted hearing aid system of Fig. 5 of Leysieffer '790, to determine the impedance of the implanted actuator (20), according to the teachings of Leysieffer '762 and common knowledge in the art as described above, to create a test system that does not require a bidirectional interface for the implanted portion of the hearing aid system to transmit measurement data back to external portion, thus simplifying the structure of implanted portion, reducing its power requirements, and potentially improving its reliability, and perhaps most importantly, not

requiring the replacement of an existing implant in patients already having a partially-implanted hearing aid system of the type depicted in Fig. 5 of Leysieffer '790 (which does not include an impedance measuring system).

Further regarding **claim 1**, the inherent normal method of testing the quality of coupling of the actuator to a component of a patient's auditory system according to the system of Fig. 5 of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Durand as described above, would comprise positioning a test measurement device (210) external to a patient having an implanted hearing aid (220) that includes an actuator (20), wherein the test device is separate from said hearing aid (as Applicant claims "an implanted hearing aid", any part of the system that is not implanted, such as external portion 210 of Leysieffer '790 Fig. 5, is "separate from the hearing aid", as broadly as claimed); utilizing the test measurement device to obtain at least one measure of a magnetic field generated by the actuator in response to a resultant electrical signal passing through the actuator (Leysieffer '762, claim 13); and employing the at least one magnetic field measure to assess the performance of the actuator (Leysieffer '762, claim 1).

10. Regarding **claims 2-5 and 21-24**, Leysieffer '762 discloses at column 6, lines 46-63 that means are provided for objectively determining the quality of coupling between the output transducer (actuator) and the coupled auditory element based on the measured impedance. Objective determination based on measured quantities inherently comprises comparing the measured quantities to one or more predetermined

ranges. Also, in a digital system, as generally disclosed by Leysieffer '762, an analog test measure must be converted to a digital value by an analog-to-digital (A-to-D) converter; such an A-to-D conversion inherently comprises comparing the (analog) test measure to a plurality of (at least partially non-overlapping) predetermined ranges (the ranges corresponding to the set of possible digital values producible by the A-to-D converter according to its resolution). This comparison is performed to assess performance parameters of the hearing aid and implanted actuator. Leysieffer '762 discloses at column 13, line 66 through column 14, line 7 that the microcontroller of the hearing aid system communicates bi-directionally with an external programming system, which can advantageously be a PC-based system with the corresponding programming, processing, display, and administration software. Although Leysieffer '762 does not explicitly disclose the detailed nature of the output provided to the operator of the system, one of ordinary skill in the art would conclude that means are included within the programming system to provide a user-interface output, via a display of the PC-based programming system, indicative of whether the measured quantities are within predetermined ranges. Leysieffer '762 discloses at column 8, lines 23-29 that impedance is measured at resonance frequencies. Objective determination based on measured quantities inherently comprises comparing the measured quantities (magnetic field measures in the system of Leysieffer '762, modified according to the teachings of Leysieffer '790 and Durand) to one or more predetermined ranges (e.g., the graduations of an arbitrary scale) using appropriate means; and testing the quality of the actuator coupling to an auditory element as disclosed by Leysieffer will inherently

indicate if the hearing aid is operational and thus will implicitly facilitate assessment of the operability of the hearing aid as alternatively claimed in claim 21or 23 and claim 2 or 4. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to compare the measured impedance value obtained by the system of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Durand as described above with regard to claims 1 and 20, with any desired number of predetermined ranges which are at least partially non-overlapping, utilizing appropriate means, in order to categorize the test results. Further, it would have been obvious to make a plurality of ranges at least partially non-overlapping, since if the ranges were not at least partially non-overlapping, they would be identical and the results of the comparisons would duplicate each other. Also, one of ordinary skill in the art would conclude that means are included and utilized in the system of Leysieffer '762 to provide an output indicative of whether the measured quantities are within the predetermined ranges, otherwise the results of the measurements would be useless and the device would be non-functional with respect to the desired test function.

11. Regarding **claims 7 and 25**, as broadly as claimed, any test signal has a frequency that is within some (predetermined) range of a resonant frequency of an actuator. Additionally, Leysieffer '762 discloses at column 8, lines 23-29 that impedance is measured at resonance frequencies, which inherently requires the signal generator to output test signals at those resonant frequencies.

12. Regarding **claim 8**, in the partially-implanted hearing aid system of Fig. 5 of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Durand, the test device (comprising an external signal processor and programming system of the hearing aid system, generally as 30 and 120 of Fig. 5 of Leysieffer '790) is "selectively interconnected" to an external transmitter (170) of the hearing aid (the transmitter or transmitter type is presumably selected to operate properly with the other elements of the system to which it is interconnected), and according to the general disclosures of Leysieffer ('790 and '762), at least one predetermined test signal is transmitted from the test device (comprising 30 and 120 of Fig. 5 of '790 patent) to the external transmitter (170); and the at least one test signal is inductively coupled between the external transmitter and a subcutaneous coil (190) of the hearing aid.

13. Regarding **claim 9**, Official Notice is taken that at the time the present invention was made, it was notoriously well known to supply acoustic test signals a hearing aid through a microphone of the hearing aid in order to test the operation of the hearing aid. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to apply this well-known method to the system of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Durand as described above with regard to claim 1, by supplying test signals to the hearing aid of Leysieffer '790 Fig. 5 through microphone 10 in order to simplify the structure of the external portion (210) of the hearing aid system.

14. Regarding **claim 16**, the normal method of use of the remote current sensor of Durant according to Fig. 1a would include obtaining a first measurement of the magnetic field at a first location (the location of sensor A, element 20); obtaining a second measurement of the magnetic field at a second location (the location of sensor B, element 22); providing an output indicative of the first and second measurements of the magnetic field (the output including a measure of the current, "I" and the distance, "r" from sensor A (20) to the source of the magnetic field as described at column 4, lines 1-12). In the system of Leysieffer '790, modified as described above to include the remote current sensor of Durant, it would have been obvious to one of ordinary skill in the art at the time the present invention was made to use the calculated distance output, "r" to determine a desired position of the test device that is as close as possible to the source of the magnetic field in order to achieve maximum accuracy in the obtained current measurement.

15. Regarding **claims 17 and 26**, Leysieffer '762 discloses at column 8, lines 1-17 that impedance measurements are made at frequencies extending over the entire transmission frequency range of the output transducer (actuator), which inherently requires providing a plurality of predetermined test signals having different frequencies distributed across a predetermined frequency range to cause a corresponding plurality of electrical signals to pass through the actuator, wherein the plurality of predetermined

test signals are at a corresponding plurality of different frequencies distributed across a predetermined frequency range.

16. Regarding **claims 18 and 27**, in the system of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Durand as described above, the system would be configured to measure a plurality of magnetic field measures corresponding to the plurality of electric signals passing through the actuator and the normal method of utilizing the test device would include using the test device to obtain a plurality of magnetic field measures corresponding to the plurality of electrical signals passing through the actuator.

17. Regarding **claim 19**, Leysieffer '762 discloses at column 8, lines 23-31, detecting (and thus identifying) the spectral distribution of resonance frequencies of the transducer in the course of the impedance measured as a function of the frequency of the stimulation signal.

18. Regarding **claim 31**, the system of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Durand as described above, comprises an oscillator (e.g., DSP 13 of Leysieffer '762) for generating the at least one test signal; a test control processor (the processor of the programming system 120 of Leysieffer '790, or 22 of Leysieffer '762) to set the oscillator to generate the at least one test signal; and a

reference transmitter (element 169 of Fig. 5 of Leysieffer '790) to provide the test signal to an external transmitter (170) of the hearing aid.

19. Regarding **claim 32**, the remote current sensor system of Fig. 1a of Durant comprises a pair of sensors (20 and 22) for measuring the magnetic field of an implanted device. Durand discloses at column 3, lines 37-38 that the sensors may include, but are not limited to magneto-sensors such as the Phillips K210. Official notice is taken that it was notoriously well known in the art at the time the present invention was made to utilize conductive coils to obtain a quantitative measure of a surrounding time-varying (AC) magnetic field. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to utilize a pair of coils as the magnetic field sensing elements in the system of Durant, incorporated into the external unit (210) of Fig. 11 of Leysieffer '790, modified according to the teachings of Leysieffer '762 as described above, to obtain a measure of the current passing through the implanted actuator.

20. Regarding **claim 33**, Leysieffer '790 discloses at column 3, line 20 –column 4, line 4 several possible actuators (transducers) that may be used with the invention, and at lines 39-46 and 58-63 discloses two that operate on electrodynamic principles. Leysieffer '762 also discloses at column 18, lines 31-34 that the electromechanical output transducer generally may be designed as any electromagnetic, electrodynamic, piezoelectric, magnetostrictive, or dielectric transducer. An electrodynamic transducer

for a partially- or fully-implanted hearing aid system would inherently include a vibratory member to stimulate a component of the auditory system.

21. Regarding **claim 37**, in the partially implanted hearing aid system and method of Fig. 5 of Leysieffer '790, modified according to the teachings of Leysieffer '762 and Durand as described above with regard to claim 20, the test device (comprising elements 30 and 120) includes said signal processing unit (30).

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. **Claim 34** is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 and 20 of U.S. Patent No. 6,712,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because The combination of claims 14 and 20 of the issued patent (each including the limitations of claim 11 of that patent) forms a method for

assessing the performance of a hearing aid that includes an implanted hearing aid actuator, comprising: positioning a test device external to a patient having an implanted hearing aid that includes a hearing aid actuator (claim 14); utilizing the test device to measure a magnetic field generated by the hearing aid actuator responsive to an electrical signal passing through the hearing aid actuator (claim 20); employing the at least one magnetic field measurement to assess an interface between the actuator and a component of an auditory system of the patient (claim 11); and providing an electrical input to a positioning system, responsive to said assessment of said interface, to selectively position the hearing aid actuator relative to the component of the auditory system (claim 11). It would have been obvious to one of ordinary skill in the art to combine these steps of the issued patent in order to form a complete method.

24. **Claim 35** is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 14, and 20 of U.S. Patent No. 6,712,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because The combination of claims 12, 14, and 20 of the issued patent (each including the limitations of claim 11 of that patent) forms a method for assessing the performance of a hearing aid that includes an implanted hearing aid actuator, comprising: positioning a test device external to a patient having an implanted hearing aid that includes a hearing aid actuator (claim 14); utilizing the test device to measure a magnetic field generated by the hearing aid actuator responsive to an electrical signal passing through the hearing aid actuator (claim 20); employing the at

least one magnetic field measurement to assess an interface between the actuator and a component of an auditory system of the patient (claim 11); and providing an electrical input to a positioning system, responsive to said assessment of said interface, to selectively position the hearing aid actuator relative to the component of the auditory system (claim 11), wherein the step of providing the electrical input comprises providing a wireless signal to the positioning system from a position external to the patient (claim 12). It would have been obvious to one of ordinary skill in the art to combine these steps of the issued patent in order to form a complete method.

25. **Claim 36** is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 14, and 20 of U.S. Patent No. 6,712,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because The combination of claims 13, 14, and 20 of the issued patent (each including the limitations of claim 11 of that patent) forms a method for assessing the performance of a hearing aid that includes an implanted hearing aid actuator, comprising: positioning a test device external to a patient having an implanted hearing aid that includes a hearing aid actuator (claim 14); utilizing the test device to measure a magnetic field generated by the hearing aid actuator responsive to an electrical signal passing through the hearing aid actuator (claim 20); employing the at least one magnetic field measurement to assess an interface between the actuator and a component of an auditory system of the patient (claim 11); and providing an electrical input to a positioning system, responsive to said assessment of said interface, to

selectively position the hearing aid actuator relative to the component of the auditory system (claim 11), wherein the step of providing the electrical input comprises inductively coupling the electrical input to the positioning system (claim 13). It would have been obvious to one of ordinary skill in the art to combine these steps of the issued patent in order to form a complete method.

Response to Arguments

26. Regarding Applicants' argument that the present invention is allowable over the prior art because claims 1 and 20 recite a test device that is separate from the hearing aid, whereas part of the test circuitry of Leysieffer '762 is contained within the hearing aid itself, as noted in the rejection of these claims above, since the claims recite an "implanted hearing aid", any part that is not implanted, such as the external portion (210) of the partially-implanted hearing aid of Fig. 5 of Leysieffer '790 can be considered as separate from the implanted hearing aid. Alternatively, the production of a spare external unit (210) for use by an audiologist or other practitioner in testing a partially-implanted hearing aid system of the type in that figure is per-se obvious, as it is well known to employ spare system components to test and troubleshoot electrical systems, and would result in a test device that is unquestionably separate from and positionable external to a patient having the implanted hearing aid.

27. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). While Applicants argue that "Durand fails to disclose or suggest, *inter alia*, an arrangement in which a test device may be utilized to generate a test signal for use in the assessment of the performance of a hearing aid that includes an implanted actuator" and "Indeed Durand fails to make any provision for the generation of such a test signal", that portion of the invention is taught by Leysieffer (in '790 and '762 patents). Leysieffer '762 teaches measuring the current in an implanted hearing aid actuator to determine the impedance of the actuator, and thereby determine the quality of mechanical coupling between the actuator and an element of the middle ear of a patient; Durand teaches a system and method for non-invasively measuring a current in an implanted medical device (column 1, lines 11-14), that is shown therein as an (equivalent) alternative to the method of interrupting a conductor to place a current sensing element in series with the conductor (column 1, lines 33-36), as is done to place current-sensing resistor Rm in series with the conductor connecting to actuator 16 in Fig. 2 of Leysieffer '762. Thus, the combination the teachings of Leysieffer '762 and Durand, applied to the partially-implanted hearing aid of Fig. 5 of Leysieffer '790, leads to the claimed invention, and the motivation to combine these teachings comes from Durand (the showing of advantages of non-invasive current measurement and equivalence for the

purpose of measuring current in an implanted device).

28. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the references is present in the references. Leysieffer '762 discloses an improved method and system for determining the quality of coupling between an implanted hearing aid actuator, which is an objective of Leysieffer '790. Durand discloses an improved method for measuring a current in an implanted medical device, as required by the method of Leysieffer, which is shown to be an equivalent method for obtaining such a current measurement.

Conclusion

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tony M. Jacobson whose telephone number is 571-272-7521. The examiner can normally be reached on M-F 11:00-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sinh N. Tran can be reached on 571-272-7564. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tmj
June 9, 2005

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SUPERVISORY PATENT EXAMINER